510(k) Summary

FEB 15 2013

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: k122177

Submitter SEPPIM S.A.S.
Address Zone Industrielle, 61500 SEES, FRANCE
Phone number + 33 (0)2 33 81 21 00
Fax number + 33 (0)2 33 28 77 51

Contact Valérie GOURDON (Email: v.gourdon@elitechgroup.com)

Date of Preparation July 9, 2012

Device names

CALIBRATOR

Trade/proprietary Name: ELITech Clinical Systems URINE TOTAL PROTEIN standard 100 mg/dL

Common or Usual Name: Calibrator, "URINE TOTAL PROTEIN Standard 100 mg/dL"

Device Class: Class II

Classification name: CFR 862.1150 – calibrator

Product code: **JIT** – Calibrator, Secondary

Predicate device HORIBA ABX PENTRA TPU Cal (K092570)

Device description ELITech Clinical Systems URINE TOTAL PROTEIN Standard 100 mg/dL is an aqueous solution ready to use containing bovine albumin at a concentration of 100 mg/dL and sodium azide (< 0.1 %).

Intended Use ELITech Clinical Systems URINE TOTAL PROTEIN Standard 100 mg/dL is intended for the calibration of quantitative ELITech Clinical Systems URINE TOTAL PROTEIN on ELITech Clinical Systems Selectra Pro Series Analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device (URINE TOTAL PROTEIN Standard 100 mg/dL)	Predicate device (HORIBA ABX PENTRA TPU Cal (K071779)
Intended use	ELITech Clinical Systems URINE TOTAL PROTEIN Standard 100 mg/dL is intended for the calibration of quantitative ELITech Clinical Systems URINE TOTAL PROTEIN on ELITech Clinical Systems Selectra Pro Series Analyzers.	ABX Pentra TPU Cal is used to calibrate total proteins in urine measurement with ABX Pentra Urinary Proteins CP on ABX Pentra 400 Analyzers.
Format	Aqueous solution ready to use containing bovine albumin and sodium azide.	A liquid ready to use calibrator based on an aqueous solution containing human serum and sodium azide.
Levels	Single level	Single level
Traceability	Traceable with SRM 927d	Traceable with SRM927
Stability	- Before opening: Each standard is stable until the expiry date stated on the label. - After opening: Each standard vial is stable for 3 months when stored tightly-closed at 2-8 °C.	In unopened vials, the calibrator is stable up to the expiry date written on the label if stored at 2-8 °C. Once opened, the calibrator is stable for 9 weeks when stored tightly recapped at 2-8°C.

Conclusion The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate devices is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

Device names

CONTROLS

Trade/proprietary Name: **ELITech Clinical Systems URINE CONTROL BI-LEVEL**

Common or Usual Name: Control, **"URINE CONTROL BI-LEVEL"**

Device Class: Class I

Classification name: CFR 862.1660 – Quality control material (assayed and unassayed).

Product code: JJX – Control, Single analyte.

Predicate device Biorad Liquicheck Urine Chemistry Control Level 1 and Level 2 (K020817).

Device description ELITEch Clinical Systems URINE CONTROL BI-LEVEL is a liquid solution prepared from human urine supplemented with constituents of human and animal origin, chemicals, preservatives and stabilizers.
These controls are prepared exclusively from the human urine where each urine donation is tested individually and found to be negative for HbsAg and to

antibodies to HCV and HIV-1/HIV-2 according to FDA-approved methods.

Intended Use

ELITech Clinical Systems URINE CONTROL BI-LEVEL is a set of 2 levels of urine controls used for *in vitro* diagnostic in the quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Pro Series Analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device (URINE CONTROL BI-LEVEL)	Predicate device (Biorad Liquicheck Urine Chemistry Control, Level 1 and Level 2 (K020817))
Intended use	ELITech Clinical Systems URINE CONTROL BI-LEVEL is a set of 2 levels of urine controls for *in vitro* diagnostic used in the quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Pro Series Analyzers	Liquicheck Urine Chemistry Control is intended for use as an assayed quality control urine.
Format	Liquid ready to use, a liquid solution prepared from human urine supplemented with constituents of human and animal origin, chemicals, preservatives and stabilizers.	Liquid form, prepared from human urine supplemented with constituents of human and animal origin, chemicals, preservatives and stabilizers.
Levels	2 Levels	2 Levels
Stability	- Before opening: Each control is stable until the expiry date stated on the label. - After opening: Each control vial is stable for 30 days when stored tightly-closed at 2-8 °C.	Product is stable until the expiration date when stored unopened at 2 to 8 °C. Once the control is opened, it is stable 30 days when stored tightly capped at 2 to 8 °C.

Conclusion

The performance data and other information demonstrate that the safety and effectiveness of these devices versus the predicate devices are not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 15, 2013

ELITechGroup
c/o Debra K. Hutson
21720 23rd Dr, S.E., Suite 150
Bothell, WA 98021

Re: k122177
Trade/Device Name: ELITech Clinical Systems URINE TOTAL PROTEIN Standard 100 mg/dL
ELITech Clinical Systems URINE CONTROL BI-LEVEL
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT, JJX
Dated: December 27, 2012
Received: December 31, 2012

Dear Ms. Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): __k122177_____

Device Name: ELITech Clinical Systems URINE TOTAL PROTEIN Standard 100 mg/dL

Indications for Use:

ELITech Clinical Systems URINE TOTAL PROTEIN Standard 100 mg/dL is intended for the calibration of quantitative ELITech Clinical Systems URINE TOTAL PROTEIN on ELITech Clinical Systems Selectra Pro Series Analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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Indications for Use Form

510(k) Number (if known): __k122177_____

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Indications for Use:

ELITech Clinical Systems URINE CONTROL BI-LEVEL is a set of 2 levels of urine controls used for *in vitro* diagnostic in the quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Pro Series Analyzers.

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